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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/752,899	12/29/2000	Frank J. Bunick	MCP-0262	9623

7590 06/08/2010

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EXAMINER	
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ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
06/08/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/752,899	BUNICK ET AL.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,8,9 and 11-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,8,9 and 11-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of RCE, response and declaration all dated 4-22-10 is acknowledged.

Claims 1-3, 5, 8, 9 and 11-14 are pending in the instant application.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4-22-10 has been entered.

The following rejection of record has been withdrawn:

Claims 1-3, 5, 8-9 and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,667,050 B1 to Boissonneault et al ('050) in view of US 3,619,292 to Brouillard ('292) OR US 6,667,050 B1 to Boissonneault et al ('050) and US 4,684,534 to Valentine ('534) in view of US 3,619,292 to Brouillard ('292).

Upon further search, the following new rejection has been applied:

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3, 5, 8-9 and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,667,050 B1 to Boissonneault et al ('050) in view of US

3,619,292 to Brouillard ('292) and further in view of Olmo et al OR US 6,667,050 B1 to Boissonneault et al ('050) and US 4,684,534 to Valentine ('534) in view of US 3,619,292 to Brouillard ('292) and Olmo et al.

'050 teach a chewable tablet composition comprising an active ingredient and carriers such as dextrose, microcrystalline cellulose, polyvinylpyrrolidone etc (all of which are claimed in the instant) and sucralose (examples). The examples of '050 contain sucralose as a sweetener. '050 teach the same binders and disintegrants that are also claimed in the instant invention but fail to teach dextrose monohydrate. The compositions of '050 do not necessarily require fat, non-saccharide water soluble binder or aspartame (claims 1, 8 and 11) (examples 3 and 6) and thus meet the claimed limitation. The examples of '050 teach the claimed disintegrants and lubricants (see examples) and other auxiliary ingredients of claim 12 (examples and col. 5-6).

'050 teach dextrose but not dextrose monohydrate and the claimed particle sizes.

'292 teach forming a free-flowing tablet containing a binder or a binder-filler, which is a sugar granule. The sugar granule comprises aggregates of cohered microcrystals of dextrose (abstract and col. 1, L 1- 20). According to '292 dextrose hydrate provides more advantages when employed in direct compression than in wet granulation or dry granulation because it produces a cooling effect when dissolved in the mouth, which is highly desirable for a tableted food or a pharmaceutical and can also enhance the flavor in the tablet (col. 2, L 10-35), particularly chewable drug tablets (col. 5, KL 55-58).

Olmo studied the role of directly compressible excipients based on dextrose, such as Emdex and Maltrin M510, in compressed tablets. The tablets were tested at four different hardness to give a target hardness of 2, 4, 6, 7, 9, 10 and 12 kP (page 774, col. 1). According to Olmo compressed tablets prepared with Emdex (hydrated dextrose) has a faster disintegration time and faster release than Maltrin M10 (abstract and figure 6). Olmo teaches that tablets with high bulk density and low porosity such as with Emdex imparts high flow rate (table 2) to the tablets and the high crushing strength (figure 4). Figure 3 shows the relationship between the compression force and crushing strength of the tablets with Emdex and Maltrin prepared by wet granulation or direct compression, where it is seen that the direct compressed tablets with Emdex provided higher crushing strength. Olmo concludes that the compressed tablets prepared with Emdex resulted in highest mechanical strength and yet faster disintegration compared with Maltrin.

Valentine '534 teaches a chewable tablet composition comprising excipient base materials such as carbohydrate based agglomerate materials including dextrose, dextrose monohydrate, fructose, sucrose etc., which are held together by small quantities of binding materials such as maltodextrin (col. 2-3). The carbohydrate agglomerates are in the size range of 20 to 100 microns (col. 4, L 29-35 & col. 9, lines 20-42) and particulate active agent having a particle size of about 50 microns (col. 4). '534 teaches at least 25% by weight of the carbohydrate agglomerate and in particular, claim 3 recites 90% to 99% by weight for a quick melting tablet. Valentine clearly states that the tablet is prepared by direct compression (col. 1, L 57-63).

It would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made that the particulate agglomerated carbohydrates or granules such as dextrose monohydrate (of Valentine '534 or '292 or Olmo et al) in the composition of '050 for preparing directly compressed tablets because Valentine '534 teach that dextrose and dextrose monohydrate are equally effective for compressibility, the tablets are highly compressible and also the tablets readily dissolve in minimal amounts of water in the mouth thus quickly liquefying of the active agent. Further '292 also teach that dextrose monohydrate particles disintegrate very quickly in the mouth and enhance the flavor of the tablet. Olmo also teaches directly compressible dextrose monohydrate with high strength and faster disintegration.

Claim 14 recites the same limitation i.e., the ratio of dextrose monohydrate to sucralose, which was presented previously in claim 1. Claim 1 has now been amended to delete the limitation. With respect to the ratio of dextrose monohydrate and sucralose, the example compositions of '050 contain high amounts of dextrose compared to the sweeteners such as sucralose and aspartame. In this regard, applicants have not established any unexpected advantage with the claimed ratio and accordingly choosing the appropriate amounts of binders and sweeteners to achieve the desired effect would have been within the scope of a skilled artisan.

Response to Arguments

Applicant's arguments and the declaration filed 4-21-10 have been fully considered but they are not persuasive.

The declarations shows tablet compression properties of different dextrose monohydrates, corn products Cerelose, Rouquette Lycadex and Cerestar Cpharm.

Applicants argue that they have found that the use of directly compressible dextrose monohydrate is important to the formation of the claimed tablet, as they impart a smooth, creamy texture and fast melt-away to soft tablets that are designed for chewing or dissolving in the mouth prior to swallowing. It is argued that the use of directly compressible dextrose monohydrate enables the manufacture of tablets without including fats and water soluble binders. It is argued that per Exhibit A, the results of testing performed by Applicants demonstrate that dextrose monohydrates, such as C*PHARMDEX 02011 (Glucose Monohydrate) from Cargill or LYCADEX® PF pyrogen-free dextrose monohydrate from Roquette Pharma, when used in tablet formulations, did not produce acceptable results (only one tablet out of a possible twenty tablets produced using either source of dextrose monohydrate was acceptable). On the other hand, when directly compressible dextrose monohydrate is used, e.g., CERELOSE brand of dextrose monohydrate available from Corn Products USA, the tablets produced were chewable and/or dissolved in the mouth prior to swallowing. Exhibit A shows that nine out of ten tablets produced using directly compressible dextrose monohydrate (CERELOSE brand of dextrose monohydrate) were acceptable. Applicants argue that they have not found any mention of the use of dextrose monohydrate that is directly compressible in making a tablet capable of being chewed or disintegrated in the oral cavity prior to Applicants' invention, as recited in Claim 1. It is submitted that Exhibit B (obtained from each company's website), shows that only

CERELOSE brand of dextrose monohydrate indicates that it is directly compressible. Neither C*PHARMDEX 02011 (Cargill) or LYCADEX® PF (Roquette Pharma) state that they are directly compressible forms of dextrose monohydrate. Applicants again submit that Boissonneault et al., Brouillard et al. and Valentine are not seen to teach or disclose the use of a directly compressible dextrose monohydrate in chewable tablet formulations. Boissonneault et al., Brouillard et al. and Valentine all fail to appreciate the difference between dextrose monohydrate and directly compressible dextrose monohydrate. Understanding the distinction enables one to manufacture chewable tables without the use of fats and water soluble binders.

Applicants' arguments are not persuasive because firstly, the instant rejection now includes a new reference (Olmo et al), which teaches directly compressible hydrated dextrose (Emdex). It is shown in Olmo that the tablets prepared by direct compression of Emdex with drug renders higher strength, hardness and faster dissolution, which is also desired by the instant invention, compared to Maltrin M10 and other process i.e., wet granulation. Further, the examiners' arguments from the previous final rejection are also reproduced here as they are applicable to the teachings of cited prior art.

The arguments are not persuasive because the very invention of Brouillard is an improvement over the known disadvantages of preparing compression tablets (dry or wet). Brouillard teaches that the dextrose granules are compressible (abstract) and that the advantages of granules are maximized in compression (col. 2, L 20-25). If a prima

facie case of obviousness is established, the burden shifts to the applicant to come forward with arguments and/or evidence to rebut the prima facie case. See, e.g., In re Dillon, 919 F.2d 688, 692, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990). Further, arguments of counsel cannot take the place of factually supported objective evidence. See, e.g., In re Huang, 100 F.3d 135, 139-40, 40 USPQ2d 1685, 1689 (Fed. Cir. 1996); In re De Blauwe, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984). On the other hand, applicants have not shown if the dextrose monohydrate taught by Brouillard is compressible or not and merely argues that the references of record fail to teach the claimed invention. Instant claims are not limited to CERELOSE brand of dextrose monohydrate, and applicants have not shown that the dextrose hydrate taught by Brouillard is the same as C*PHARMDEX 02011 (Glucose Monohydrate) from Cargill or LYCADEX® PF. Hence, the arguments are not persuasive and the rejection has been maintained. Further, the new rejection now provides advantages of directly compressible dextrose monohydrate (Olmo et al). Therefore, the argued unexpected results are expected in light of the teachings of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
May 31, 2010